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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,360	10/15/2001	Jean-Baptiste Dumas Milne Edwards	G-056US04CIP	4722

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EXAMINER	
O HARA, EILEEN B	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,360	DUMAS MILNE EDWARDS ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,17-20 and 22-27* is/are pending in the application.

4a) Of the above claim(s) *23-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,17-20,22 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 14, 15, 17-20 and 22-27 are pending in the instant application. Claims 14, 15 and 22 have been amended, claims 16 and 21 have been canceled and claims 25-27 have been added as requested by Applicant in the Paper filed December 29, 2005.

Claims 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 14, 15, 17-20, 22 and 25-27 are currently under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14, 15, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The claims encompass a composition of matter comprising an isolated polypeptide comprising from 300 to 351 consecutive amino acids of SEQ ID NO: 437 or polypeptide comprising at least 37 consecutive amino acids of SEQ ID NO: 437. These fragments were not disclosed in the specification and are therefore new matter.

Maintained Rejections

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claims 14, 15, 17-20, 22 remain rejected and new claims 25-27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for reasons of record in the previous office action.

Applicants traverse the rejection and assert that the ability of the polypeptide identified as SEQ ID NO: 437 to serve as a transcription factor or a signal transduction molecule (as disclosed in the specification) has been confirmed by Matsuda et al., in which they show that a polypeptide identical to SEQ ID NO: 437 is a transcription factor in the activation pathway of NF-κB, which plays a pivitol role in inflammatory responses. Applicants point to paragraph 639, which teaches methods for assaying the proteins expressed from cDNAs or fragments thereof for anti-inflammatory activity.

Applicants' arguments have been fully considered but are not deemed persuasive. Although the protein of SEQ ID NO: 437 may have been identified as a transcription factor, there was no specific or substantial utility disclosed in the specification as filed, that is, no information about what DNA sequence it might bind to what gene it could activate. Although it was later identified as a transcription factor in the activation pathway of NF-κB, this was not disclosed in the specification.

For these reasons the rejection is maintained.

4.2 Claims 14, 15, 17-20, 22 and 25-27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of how to use the polypeptide of SEQ ID NO: 437, enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the polypeptide of SEQ ID NO: 437, the skilled artisan would clearly not know how to use polypeptides comprising fragments of the polypeptide of SEQ ID NO: 437 or polypeptides 85 % identical to the polypeptide of SEQ ID NO: 437.

4.3 Claims 14, and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as applied to newly amended or new claims for reasons of record in the previous office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claim 15, and the rejection over this claim is

withdrawn. However, claims 14, and 25-27 encompass a composition of matter comprising an isolated polypeptide comprising an amino acid sequence at least 85% identical to SEQ ID NO: 437, polypeptide comprising at least 37 consecutive amino acids of SEQ ID NO: 437 or polypeptide comprising amino acids 302 through 339 of SEQ ID NO: 437.

Applicants traverse the rejection and cite *In re Herschler and Purdue Pharma L.P. v. Faulding, Inc,* and *Vas-Cath, Inc. V. Mahrukar.* Applicants submit that one of ordinary skill in the art would have recognized that the specification conveyed that polypeptide fragments having a length corresponding to any who number between 8 and in the case of SEQ ID NO: 437, 352 consecutive amino acids were in possession of the integers at the time the application was filed. Applicants further submit that the specification clearly sets forth polypeptide fragments comprising at least 5 or 8 consecutive amino acids of SEQ ID NOS: 406-810, and point to original claim 2, and that in view of these passages, Applicants submit that the as-filed specification provides adequate written description of the polypeptides comprising between 6 and 351 consecutive amino acids of SEQ ID NO: 437, or in the case of newly presented claim 26, polypeptides comprising at least 37 consecutive amino acids of SEQ ID NO: 437.

Applicants' arguments have been fully considered but are not deemed persuasive. While the specification may have contemplated polypeptides comprising from 8 to 351 consecutive amino acids of SEQ ID NO: 437, for example, as written, claims 26 and 27, for example encompasses a polypeptide that may be only 10.5% homologous to the protein of SEQ ID NO: 437 (37/352 residues). Claim 14 encompasses a polypeptide that may only be 85% homologous to the polypeptide of SEQ ID NO: 437. The courts have specifically stated that the skilled artisan cannot envision the *detailed chemical structure* of an encompassed polypeptide until the structure is disclosed, and therefore conception is not

achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In the instant case, SEQ ID NO: 437 has been disclosed, but no sequence variants thereof have been disclosed. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. For claims 14 and 25-27, the only factors present in the claims are a partial structure in the form of a recitation of percent identity or comprising a small number of amino acids. While amino acids 302-339 of SEQ ID NO: 437 may be critical for binding DNA, other amino acid residues in the amino acid sequence of SEQ ID NO: 437 which are essential for its biological activity and structural integrity are not identified. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in

binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. The ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. For these reasons, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PRIMARY EXAMINER